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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,661	10/28/2003	Gerald Czygan	117163.00094	4060

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EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
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Office Action Summary

Application No.

10/695,661

Applicant(s)

CZYGAN, GERALD

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,46,50,51,55,56,60 and 61 is/are rejected.
- 7) ☒ Claim(s) 8-17,28,30,32,34,35,38-40,42,43,45,47,49,52,54,57,59,62 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,8-17,28,30,32,34,35,38-40,42,43,45-47,49-52,54-57,59-62 and 64.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2007 has been entered. Claims 2, 6-7, 18-27, 29, 31, 33, 36-37, 41, 44, 48, 53, 58 and 63 have been cancelled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-5, 46 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Prutchi et al. (U.S. 6,141,585) (herein Prutchi). As to Claim 1, Prutchi discloses a cardiac stimulator, read as a device 400 for delivering electrical stimulation pulses to body tissue through stimulation electrode 520 (see Prutchi Abstract, Figs. 4-5 and column 7, lines 15-32) comprising a tank capacitor, read as energy storage means C_T for providing electrical stimulation energy to the stimulation electrode 520 from a voltage source, read as an energy source V_i . The device 400 of Prutchi further comprises a charging switch, read as a first switch SW1 with which the energy

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storage means C_T is switchably connected to the energy source V_i for charging the energy storage means C_T (see Prutchi column 9, lines 20-53). The device 400 of Prutchi further comprises an electrode connection for connecting the stimulation electrode 520 to the device for delivering electrical stimulation pulses to body tissue and a pacing switch, read as a second switch SW2 with which the energy storage means C_T is switchably connected to the electrode connection for delivery of a stimulation pulse (see Prutchi column 9, lines 53-62). The device 400 of Prutchi further comprises an impedance circuit, read as a means for monitoring stimulation outcome 466 and a discharge switch, read as a short-circuit switch SW3 with which the electrode connection, after delivery of the stimulation pulse is switchably connected to a ground potential (see Prutchi Fig. 5) such that, in the case of a connected and implanted electrode 520 a capacitance can be discharged by way of the body tissue, where the capacitance includes at least one Helmholtz capacitance C_L produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or body tissue. The device 400 of Prutchi further comprises a processor, read as a control unit 470 which is connected to at least the first switch SW1, the second switch SW2 and the short-circuit switch SW3 for switching the respective switches and which is adapted to separate the electrode connection from the energy storage means C_T after delivery of the stimulation pulse and at least indirectly connect the electrode connection to the ground potential.

Prutchi expressly discloses that the means for monitoring stimulation outcome 466, after delivery of the stimulation pulse, is connected to the electrode connection and is adapted to detect a drop/rise in voltage over time at the Helmholtz capacitance C_L or a drop/rise in short circuit current over time at the capacitance, both representative of a characteristic drop/rise in

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myocardium impedance of the body tissue. Prutchi specifies that the measurements (of either voltage over time at the Helmholtz capacitance C_L or short circuit current over time at the Helmholtz capacitance C_L) are used to allow the control unit 470 to calculate myocardium impedance using Ohm's Law (see Prutchi Figs. 3A-3B, column 3, lines 5-67, columns 4-5, column 6, lines 1-52, column 9, lines 20-67 and columns 10-12). Although not expressly stated by Prutchi, a calculated drop in myocardium impedance inherently indicates that the pacing pulse successfully stimulated the heart tissue. Alternatively, a calculated rise in myocardium impedance inherently indicates that the pacing pulse did not successfully stimulate the heart tissue. The Examiner cites Kroll (U.S. 2001/0049543) and (Meier (U.S. 5,22,924) which both expressly teach this principle.

4. As to Claims 3-5, in addition to the above, Prutchi further discloses that the capacitance also comprises a DC blocking capacitor, read as a coupling capacitor C_B that is connected between the electrode connection and the ground potential when the short-circuit switch SW# is closed. Prutchi further discloses that the coupling capacitor C_B is arranged between the energy storage means C_T and the electrode connection in such a way that the coupling capacitor C_B is connected in series with the energy storage means C_T when the second switch SW2 is closed (see Prutchi Fig. 5).

5. As to Claim 46, Prutchi discloses that in unipolar electrode configurations, the ground potential is formed by a housing of the device or a surface portion thereof (see Prutchi Fig. 3B and column 3, lines 5-65).

6. As to Claims 50 and 51, the energy storage means is a reservoir tank capacitor C_T as discussed above.

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 55-56 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi. Prutchi discloses the claimed invention as discussed above except it is not specified that the energy source V_i include a charge pump. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi, with a charge pump since it was known in the art that charge pumps are used to provide a means to multiply or otherwise step up a voltage provided by a typical battery to a reservoir capacitor for powering an implantable medical device such as a pacemaker.

Allowable Subject Matter

9. Claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed March 6, 2007 have been fully considered but they are not persuasive. In response to Applicant's argument that Prutchi does not include certain features of Applicant's invention, the limitations on which Applicant relies (i.e. that "the myocardium

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impedance is recorded or evaluated after delivery of the stimulation pulse” – see page 12 of the Remarks) are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specification that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.*, 7 USPQ2d 1064. Also, in response to Applicant’s argument that Prutchi has a different use than that of Applicant’s, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). As written, the claims of Applicant only require that the means for monitoring stimulation outcome, at least after delivery of a stimulation pulse, be “adapted to detect” either a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance. What such drops in voltage over time at the capacitance or a rises in a short-circuit currents over time at the capacitance represent in science are matters of principle and inherency.

As previously discussed, Prutchi expressly discloses that the means for monitoring stimulation outcome 466, after delivery of the stimulation pulse, is connected to the electrode connection and is adapted to detect a drop/rise in voltage over time at the Helmholtz capacitance C_L or a drop/rise in short circuit current over time at the capacitance, both representative of a characteristic drop/rise in myocardium impedance of the body tissue. Prutchi specifies that the measurements (of either voltage over time at the Helmholtz capacitance C_L or short circuit current over time at the Helmholtz capacitance C_L) are used to allow the control unit 470 to calculate myocardium impedance using applications of Ohm’s Law (see Prutchi Figs. 3A-3B, column 3, lines 5-67, columns 4-5, column 6, lines 1-52, column 9, lines 20-67 and columns 10-

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12). Although not expressly stated by Prutchi, a calculated drop in myocardium impedance inherently indicates that the pacing pulse successfully stimulated the heart tissue. Alternatively, a calculated rise in myocardium impedance inherently indicates that the pacing pulse did not successfully stimulate the heart tissue. The Examiner cites Kroll (U.S. 2001/0049543) and (Meier (U.S. 5,22,924) which both expressly teach this principle.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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